

CERTIFICATE

Number: **2022466TE01**

EC TYPE-EXAMINATION MEDICAL DEVICES AND ANIMAL TISSUE DIRECTIVE

Issued to:

Scion Cardio-Vascular, Inc

14253 S.W. 119 Ave.

Miami, FL 33186

USA

For the product category:

Non-Woven Hydrophilic Wound Dressings (Class III)

Documents that form the basis of this certificate:

Certification Notice 2022466CN, initially dated October 1, 2002**Addendum, initially dated September 22, 2009**

KEMA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Directive 93/42/EEC of June 14, 1993 concerning Medical Devices and Animal Tissue directive, including all subsequent amendments, and that for the above mentioned product category the Conformity Assessment Procedure Annex III is executed by the Manufacturer in accordance with the provisions of the Council Directive 93/42/EEC of June 14, 1993. Additionally, KEMA hereby declares that the manufacturer fulfils the relevant provisions as specified in Annex I of the Directive 2003/32/EC of April 23, 2003 concerning medical devices manufactured utilising tissue of animal origin. The necessary information and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: **September 1, 2012**

Issued for the first time: September 22, 2009

KEMA Quality B.V.

drs. G.J. Zoetbrood
Managing DirectorM. McCann
Certification Manager

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ADDENDUM

Belonging to certificate: **2022466TE01**

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EC TYPE-EXAMINATION MEDICAL DEVICES AND ANIMAL TISSUE DIRECTIVE

Non-Woven Hydrophilic Wound Dressings (Class III)

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USA

This certificate covers the following product(s):

CLO-SUR P.A.D.

Clo-Sur Plus P.A.D

Initial date: September 22, 2009

KEMA Quality B.V.



drs. G.J. Zoetbrood
Managing Director



M. McCann
Certification Manager

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KEMA Medical

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